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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,129	07/23/2003	Michael Paul Pieper	1/1382	8804
28501	7590	08/31/2006	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			ALSTRUM ACEVEDO, JAMES HENRY	
		ART UNIT		PAPER NUMBER
		1616		
DATE MAILED: 08/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,129	PIEPER ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 22-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 21 is/are rejected.
- 7) Claim(s) 18-20 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/05;7/22/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1-27 are pending. Claims 1-14 and 18-21 are under consideration in the instant office action. Receipt and consideration of Applicants' response to the restriction requirement (mailed May 10, 2006) and IDS's (submitted 9/19/05 and 7/2204) is acknowledged.

Election/Restrictions

Claims 15-17 and 22-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 10, 2006.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1616

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-9, 11, and 23-24 of U.S. Patent No. 6,706,726 (USPN '726). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of USPN '726 claim a genus, which encompasses the anticholinergic described by formula 1 in claim 1 of the instant application or the same species (see claim 11 of USPN '726) and renders the claims of the instant application obvious. It is noted for the record that independent claim 1 of the instant application claims a pharmaceutical composition comprising (a) an anticholinergic of formula 1, (b) a betamimetic, and (c) a steroid. Dependent claims 8 and 23 of USPN '726 claim a pharmaceutical composition comprising an anticholinergic that is either a genus encompassing the specific anticholinergic claimed by Applicant (claim 8 of USPN '726) or the same anticholinergic compound (claim 23). It is noted that USPN '726 teaches an anticholinergic compound, wherein R¹ and R² are methyl substituents; A is an epoxide group; R⁷ is a C₁₋₄ alkyl (this includes methyl); R³, R⁴, R⁵, and R⁶ are hydrogen; and X⁻ is an anion with a single negative charge selected from among chloride, bromide, methylsulfate, 4-tolunesulfonate, and methylsulfonate (col. 2, lines 36-60, line 66; col. 3, lines 24-28; Example 5, and claims 1-2 and 11), wherein said teachings/claims define the same anticholinergic compound depicted by formula 1 in claim 1 of the instant application. Dependent claims 11 and 24 of USPN '726 claim a pharmaceutical composition also comprising additional

active agents including betamimetics and steroids. USPN '726 is silent regarding the ratios of anticholinergic to betamimetic or steroid and the total amount of drug, as claimed in dependent claims 11-14 of the instant application. It is the Examiner's position that the broad ratios of anticholinergic to betamimetic or steroid and total amount of drug claimed by Applicant are ranges that a skilled artisan would have obtained upon routine optimization of active agent amounts. Applicants have not demonstrated the criticality of the specific claimed anticholinergic: betamimetic or anticholinergic: steroid ratios and total drug amounts.

Claims 1-12 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/273,782 (copending '782). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Independent claim 1 of the instant application claims a pharmaceutical composition comprising (a) an anticholinergic of formula 1, (b) a betamimetic, and (c) a steroid. Independent claim 1 of copending '782 claims a pharmaceutical composition comprising (a) an anticholinergic of formula 1, wherein the chemical structure of formula 1 in copending '782 is the same as the formula 1 chemical structure of the instant application, (b) salmeterol xinafoate, or a hydrate, solvate, enantiomer or mixtures of enantiomers thereof, and (c) a steroid selected from ciclesonide, budesonide, and mometasone furoate, or a solvate or hydrate thereof. Salmeterol xinafoate is a well-known betamimetic, and is acknowledged as being a betamimetic by Applicant in dependent claims 9-10 of the instant application. The specific steroids claimed in independent claim 1 of copending '782 are also

identified as being steroids in dependent claims 7-8 of the instant application. The dependent claims of both the instant application and copending '782 obviously claim the same and/or substantially similar limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/274,648 (copending '648). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are substantially overlapping in scope and mutually obvious. Independent claim 1 of the instant application claims a pharmaceutical composition comprising (a) an anticholinergic of formula 1, (b) a betamimetic, and (c) a steroid. Independent claim 1 of copending '648 claims a pharmaceutical composition comprising (a) an anticholinergic of formula 1, wherein the chemical structure of formula 1 in copending '648 is the same as the formula 1 chemical structure of the instant application, (b) a formoterol salt selected from formoterol fumarate, formoterol hemifumarate, or a hydrate, solvate, enantiomer or mixtures of enantiomers thereof, and (c) a steroid selected from ciclesonide, budesonide, and mometasone furoate, or a solvate or hydrate thereof. Formoterol is a well-known betamimetic, and is acknowledged as being a betamimetic by Applicant in dependent claims 9-10 of the instant application. The specific steroids claimed in independent claim 1 of copending '648 are also identified as being steroids in dependent claims 7-8 of the

instant application. The dependent claims of both the instant application and copending '648 obviously claim the same and/or substantially similar limitations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-14 and 21 are rejected. Claims 18-20 are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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